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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,915	11/12/2008	Ning Hu	01992.001US2	1645

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1612	
MAIL DATE	DELIVERY MODE
01/23/2012	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,915	HU ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, PhD	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2012*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,5,9,12,14,15,17,18,22,26,37 and 42* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,5,9,12,14,15,17,18,22,26,37 and 42* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 1-6-12 is acknowledged.

Claims included in the prosecution are 1, 5, 9, 12, 14-15, 17-18, 22, 26, 37 and 42.

In view of the amendments to the claims, the 102 rejections of claims over Durr and EP have been withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 5, 9, 12, 14-15, 17-18, 22, 26, 37 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amended claim 1 recites Trademark 'Tomudex R' which is improper. "Amikacin" is misspelled in claim 1.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 5, 9, 12, 17, 18, 22, 26, 37 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/13053 of record.

WO discloses liposomal preparations containing phosphatidylcholine, a negatively charged phospholipid and Taxol. (Abstract and Example 1). Although WO does not specifically teach the mean particle sizes of the liposomes to be less than 100, since it teaches passing the liposomes through 0.1 micron filters, particles of less than 100 is implicit.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Straubinger discloses a composition that includes at least one taxane present in a pharmaceutical effective amount and a mixture of one or more negatively charged phospholipids and one or more zwitterion (i.e. uncharged) phospholipids and that Straubinger does not disclose the preparation of liposomes comprising the therapeutic agents of claim 1.

These arguments are not persuasive. According to the currently amended claim 1, the antineoplastic agents include paclitaxel. Straubinger teaches taxol which is another name for paclitaxel. The examiner cites US 2012/0009251 (see 0042), US 2011/0250259 (see 0011) and US 2002/0034538 (see 0086) in this context.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 5, 9, 12, 14-15, 17-18, 22, 26, 37 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durr et al (Eur. Journal of Pharmaceutics and Biopharmaceutics, 1994) of record by itself or in combination with Rahman (6,461,637).

Durr as pointed out in the previous action discloses liposomes containing soya phosphatidylcholine and either DMPG or soya phosphatidic acid. The sizes of the liposomes are less than 100 nm (pages 149 and 150). Although Durr uses doxorubicin in the preparations, Durr's statements on page 156, col. 1 indicate the applicability of the liposomal formulations to drugs in general and therefore, it would have been obvious to one of ordinary skill in the art to encapsulate any drug with a reasonable expectation of success. One of ordinary skill in the art would be motivated to use paclitaxel as the active agent since the reference of Rahman teaches that paclitaxel can be encapsulated in liposomes (Abstract, col. 3, lines 41-56, Example 1). Durr uses soya phosphatidylcholine and does not teach the use of Egg phosphatidylcholine; however, it would have been obvious to one of ordinary skill in the art that liposomal formation occurs irrespective of the source of the phosphatidylcholine. Therefore, one of ordinary skill in the art would use egg PC with a reasonable expectation of success.

7. Claim 15 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Durr by itself or in combination with Rahman as set forth above in view of EP both cited above.

The teachings of Durr have been discussed above. As discussed above, Durr does not teach the use of Egg PC. However, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art with a reasonable expectation of success to use Egg PC since EP teaches the routine practice of using Egg PC in liposomal formulations. Although Durr does not teach claimed ratios of the phospholipid to the drug, since the amount of drug depends upon the condition to be treated, it is deemed obvious to one of ordinary skill in the art to manipulate the amounts especially in view of the teachings of the claimed ratios by EP.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant provides no specific arguments regarding the 103 rejections.

8. Claims 1, 5, 9, 12, 14-15, 17-18, 22, 26, 37 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/13053 of record by itself or in combination with Rahman (6,461,637).

As pointed out above, WO teaches the encapsulation of taxol in negatively charged liposomes. Even assuming that taxol taught by WO is not paclitaxel, it is deemed obvious to one of ordinary skill in the art to encapsulate paclitaxel since the reference teaches that any taxane can be encapsulated within the anionic liposomes (see page 13, line14-21). One of ordinary skill in the art would be motivated to

encapsulate paclitaxel as the active agent since the reference of Rahman teaches that paclitaxel can be encapsulated in liposomes (Abstract, col. 3, lines 41-56, Example 1).

9. Claims 1, 5, 9, 12, 14-15, 17-18, 22, 26, 37 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lakkaraju (US 2003/0026831).

Lakkaraju discloses anionic liposomes containing phosphatidylcholine and an anionic phospholipid. The diameters taught by Lakkaraju are from 75 nm to 500 nm. The therapeutic agents taught by Lakkaraju include immunosuppressants, anti-neoplastic agents, anti-fungal agents, anti-inflammatory agents, cephalosporins (Abstract, 0045-0047; 0056-0057;0073-0087; 0102-0103;0137-0138). Although Lakkaraju does not teach the specific anti-neoplastic agent, immunosuppressants and anti-bacterial agents, in view of his generic teachings, and from the guidance provided it would have been obvious to one of ordinary skill in the art to encapsulate any active agent with a reasonable expectation of success. Although Lakkaraju does not teach the sizes of the liposomes to be less than 100 nm in view of the lower range of 75 nm taught by Lakkaraju, one of ordinary skill in the art would be motivated to manipulate the sizes in order to obtain the best possible results. Lakkaraju does not teach the use of egg phosphatidylcholine; however, since phosphatidylcholines are known to form liposomes and since Lakkaraju teaches phosphatidylcholine, one of ordinary skill in the art would be motivated to use phosphatidylcholine from any source with a reasonable expectation of success.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, PhD whose telephone number is (571)272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S. Kishore/
Primary Examiner, Art Unit 1612

GSK